

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
 RYAN KROMHOLZ & MANION, S.C.
 P.O. BOX 26618
 MILWAUKEE, WI 53226

NOTIFICATION OF TRANSMITTAL OF
 THE INTERNATIONAL SEARCH REPORT AND
 THE WRITTEN OPINION OF THE INTERNATIONAL
 SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 20835-PCT	Date of mailing <i>(day/month/year)</i> 24 JUL 2009
International application No. PCT/US 09/02403	International filing date <i>(day/month/year)</i> 17 April 2009 (17.04.2009)
Applicant MIRAMAR LABS, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 8270

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: <p style="text-align: center;">Lee W. Young</p> PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
---	--

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 20835-PCT	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 09/02403	International filing date (<i>day/month/year</i>) 17 April 2009 (17.04.2009)	(Earliest) Priority Date (<i>day/month/year</i>) 17 April 2008 (17.04.2008)
Applicant MIRAMAR LABS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/02403

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: 1-26, drawn to towards disposal housings, particularly intended for use with medical devices

Group II: 27-61: Method and devices with antenna arrays, scattering elements and cooling plates to apply energy to the skin.

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a disposable housing, particularly the casing, intended for use with general medical devices, which is not present in Group II. Group II has a special technical feature of antenna arrays, scattering elements and cooling plates for applying energy to skin, which is not present in Group I. Neither of these special technical features is shared by the other group, nor do they correspond to a special technical feature in the other group. Accordingly, unity of invention is lacking under PCT Rule 13.1.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-26

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/02403

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 18/18 (2009.01)

USPC - 607/101

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

USPC: 607/101

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 607/96-101, 104

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB), Google patent, Google Scholar
Search Terms: apparatus, methods, systems, tissue, noninvasive treatment, energy, therapy, dermatological, generator, applicator, disposable, tissue chamber, applicator chamber, opening, bio-barrier (hydrophobic filter), rigid surface, compliant member, angle

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0251117 A1 (ANDERSON et al) 10 November 2005(10.11.2005) entire document, especially para[0040], [0051], [0060], [0071], [0073], Fig. 3	14, 22-23, 26
--		15-21, 24-25
Y	US 6,334,074 B1 (SPERTELL) 25 December 2001 (25.12.2001) entire document, especially col 4, ln 67-col 5, ln 8; col 6, ln 8-12; col 7, ln 23-26; col 7, ln 49-51; col 7, ln 54-61; col 7 ln 67-col 8, ln 8; col 8, ln 39-43; col 8, ln 47-63; col 9, ln 32-41; Fig. 4-7, 12	1-13, 24-25
Y	US 7,278,991 B2 (MORRIS et al) 09 October 2007 (09.10.2007) col 7, ln 48 -51	1-13
Y	US 6,277,104 B1 (LASKO et al) 21 August 2001 (21.08.2001) col 7, ln 25-34	15-21
Y	US 2004/0049251 A1 (KNOWLTON)11 March 2004 (11.03.2004)para[0024], [0201]	11-12
Y	US 6,457,476 B1 (ELMER et al) 01 October 2002 (01.10.2002) col 9, ln 50-53	13

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

15 July 2009 (15.07.2009)

Date of mailing of the international search report

24 JUL 2009

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:
RYAN KROMHOLZ & MANION, S.C.
P.O. BOX 26618
MILWAUKEE, WI 53226

Date of mailing
(day/month/year)

24 JUL 2009

Applicant's or agent's file reference
20835-PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US 09/02403

International filing date (day/month/year)
17 April 2009 (17.04.2009)

Priority date (day/month/year)
17 April 2008 (17.04.2008)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 18/18 (2009.01)
USPC - 607/101

Applicant MIRAMAR LABS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis. 1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion
15 July 2009 (15.07.2009)

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 09/02403

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 09/02403

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

☐ complied with

☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: 1-26, drawn to towards disposal housings, particularly intended for use with medical devices

Group II: 27-61: Method and devices with antenna arrays, scattering elements and cooling plates to apply energy to the skin.

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a disposable housing, particularly the casing, intended for use with general medical devices, which is not present in Group II. Group II has a special technical feature of antenna arrays, scattering elements and cooling plates for applying energy to skin, which is not present in Group I. Neither of these special technical features is shared by the other group, nor do they correspond to a special technical feature in the other group. Accordingly, unity of invention is lacking under PCT Rule 13.1.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☐ all parts

☒ the parts relating to claims Nos. 1-26

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 09/02403

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-10, 11-13, 15-21, 24, 25	YES
	Claims	14, 22-23, 26	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-26	NO
Industrial applicability (IA)	Claims	1-26	YES
	Claims	None	NO

2. Citations and explanations:

Claims 14, 22-23, 26 lack novelty under PCT Article 33(2) as being anticipated by US 2005/0251117 A1 to Anderson et al (hereinafter "Anderson").

As per claim 14, Anderson discloses a medical device disposable (FIG. 9) comprising:
a tissue chamber (portion of concave opening below 301, FIG. 3) comprising a tissue contact surface (301) at a proximal end of said tissue chamber and a tissue opening at a distal end of said tissue chamber (para[0051], FIG. 3);
an applicator chamber (interior of 300 and portion above 301, FIG. 3; para[0051]);
a flexible bio-barrier at a proximal end of said tissue chamber said flexible bio-barrier separating said tissue chamber and said applicator chamber, said flexible bio-barrier (301) forming at least a portion of said tissue contact surface (para[0051]) "Membrane 301 can be used to collect dead skin, ...";
a vacuum port (304, para[0051]);
a vacuum circuit connecting said tissue chamber, said applicator chamber and said vacuum port, said vacuum circuit comprising a vacuum passage (para[0073]) "The membrane 301 has two portions: an interior portion 1101A which generates an interior vacuum...".

As per claim 22, Anderson discloses the medical device disposable further comprising a compliant member (301) surrounding said tissue opening, said compliant member having a proximal opening adjacent said tissue opening and a distal opening, wherein said distal opening is larger than said proximal opening (para[0051]) "A recess or void exists between the membrane 301...", Fig. 3 shows the distal opening is larger than said proximal opening).

As per claim 23, Anderson discloses the medical device disposable wherein said vacuum passage is an opening between a wall of said tissue chamber and said tissue bio-barrier (FIG. 3, para[0073]) "The membrane 301 has two portions: an interior portion 1101A...".

As per claim 26, Anderson further discloses the medical device disposable wherein said tissue surface (184) has an area greater than an outer area of an antenna array (172) in an applicator affixed to said medical device disposable (para[0060]) "The electrodes 403a and 403b in FIG. 4 can serve two purposes...", para[0071] "The disposable tip 902 on device 900 may be...").

Claims 1-10 lack an inventive step under PCT Article 33(3) as being obvious over US 6,334,074 B1 (Spertell) in view of US 7,278,991 B2 to Morris et al (hereinafter "Morris").

As per claim 1, Spertell discloses a medical device disposable comprising (col 7, ln 49-51):
a tissue chamber (82) having a tissue opening (84) at a distal end and a rigid surface surrounding said tissue opening (col 7, ln 54-55; col 7 ln 67-col 8, ln 2);
an applicator chamber (69) (col 7, ln 23-26);
a flexible bio-barrier at a proximal end of said tissue chamber said flexible bio-barrier (83) separating said tissue chamber and said applicator chamber, a portion of said flexible bio-barrier forming a tissue contacting surface (col 8, ln 51-56); However, Spertell fails to teach a compliant member. Morris discloses a compliant member surrounding said tissue opening, said compliant member having a proximal opening adjacent said tissue opening and a distal opening, wherein said distal opening is larger than said proximal opening (col 7, ln 48-51). It would have been obvious to one skilled in the art combine the compliant member taught by Morris to the device of Spertell so that the treatment device has flexible tissue chamber which can be better sealed with the treated surface of the tissue.

As per claim 2 and 3, Spertell discloses the medical device disposable wherein said compliant member is positioned at an angle, or comprises a wall connecting said proximal opening and said distal opening, said wall being angled of approximately fifty-three degrees with respect to said rigid surface (col 7, ln 67-col 8 ln 4, claim 12). Although Spertell does not describe how big the angle, however, it would have been obvious to one skilled in the art make the angle to 53 degree easily as needed.

As per claim 4, Spertell further discloses the medical device disposable wherein said compliant member further comprises an outer rim positioned around said distal opening (col 9, ln 38-41).

--Please See Continuation Sheet--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 09/02403

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V.2 Citations and Explanations:

As per claim 5, Spertell further discloses the medical device disposable wherein:
said outer rim extends a distance of approximately .033 inches from said distal opening(col 7, ln 54-57);
said compliant member has a height of approximately .25 inches;
said tissue opening has a long axis and a short axis, said tissue opening long axis being approximately 1.875 inches and said tissue opening short axis being approximately 1.055 inches(col 7, ln 23-26; See Fig. 7);
said distal opening in said compliant member has a long axis and a short axis said distal opening long axis being approximately 2.429 inches and said distal opening short axis being approximately 1.609 inches(col 7, ln 23-26; See Fig. 7)
said tissue contact surface having a long and a short axis, said long axis being approximately 1.54 inches and said short axis being approximately .700 inches(col 7, ln 23-26; See Fig. 7). Although Spertell just provide few dimensions in his device, we can estimate the other dimensions based on the known dimensions and the drawings, for height of the compliant chamber, according to Fig. 7, if opening 67 is 6 mm x 4 mm = 0.236 inches x 0.157 inches, then proportionally the size of the opening of chamber 82 should be 7 mm x 5 mm = 0.275 inches x 0.197 inches, the height of chamber 82 should be around 7 mm = 0.275 inches, it would have been obvious to one skilled in the art to applicator chamber and the disposable chamber with larger size as the application, or as an optional size for device of Spertell so that the device can be used in a wider range of treatments.

As per claim 6, Spertell further discloses the medical device disposable wherein said wall is substantially straight (see Fig. 7, 80).

As per claim 7, Spertell further discloses the medical device disposable wherein said compliant member comprises one or more alignment marks, at least one of said alignment marks being positioned on a long side of said compliant member(col 8, ln 39-43).

As per claim 8, Spertell further discloses the medical device disposable wherein said alignment marks are positioned on a wall of said skirt and extend from approximately said rim toward said tissue opening(col 8, ln 4-8) .

As per claim 9, Spertell further discloses the medical device disposable wherein said alignment marks move with respect to an applicator positioned in said applicator chamber when said medical device disposable is pressed against tissue with sufficient pressure to compress said compliant member(col 7, ln 57-61).

As per claim 10, Spertell further discloses the medical device disposable wherein said wall has a thickness of approximately .050 inches(Fig. 7). According to Fig. 7 and the drawing ratio, the thickness of the disposable chamber(80) should be around 1 mm = 0.040 inches.

Claims 15-21 lack an inventive step under PCT Article 33(3) as being obvious over Anderson in view of US 6,277,104 B1 to Lasko et al (hereinafter "Lasko").

As per claim 15, Anderson discloses a medical device disposable wherein said vacuum circuit comprises:
a vacuum passage positioned around said tissue contact surface a vacuum channel positioned around said vacuum passage, said vacuum channel positioned between said vacuum passage and said vacuum port;(para[0073]"as shown in FIG. 11, there are any number of vacuum chambers A, B on device.."), however, Anderson fails to teach an air permeable and fluid impermeable bio-barrier.
Lasko discloses an applicator bio-barrier positioned between said vacuum port and said applicator chamber, said applicator bio-barrier being substantially permeable to air and substantially impermeable to fluids(col 7, ln 25-34). Therefore it would have been obvious to one skilled in the art utilize a bio-barrier as taught by Lasko with the device of Spertell in order to remain the liquid on the the treatment surface and vacuum the air from therein during the tissue treatment.

As per claim 16 and 17, Anderson discloses the medical device disposable wherein said vacuum passage completely/ substantially surrounds said tissue interface surface (para[0073]; FIG. 11).

As per claim 18, Anderson further discloses the medical device disposable wherein said vacuum passage is positioned in a wall of said tissue chamber adjacent said tissue contact surface (FIG. 3).

As per claim 19, Anderson further discloses the medical device disposable wherein said vacuum port is connected to a vacuum tube(para[0071]"The device 900 also includes a pneumatic adjustment control 903 to control ..").

As per claim 20, Lasko further discloses the medical device wherein said vacuum tube includes a generator bio-barrier said generator bio-barrier being substantially permeable to air and being substantially impermeable to fluids(col 7, ln 25-34).

As per claim 21, Anderson discloses the medical device disposable wherein said vacuum channel includes a well region adapted to collect fluids from said tissue chamber (para[0051]"Membrane 301 can be used to collect dead skin, according to one..; FIG. 3).

-Please See Continuation Sheet--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/02403

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V.2 Citations and Explanations:

Claims 24-25 lack an inventive step under PCT Article 33(3) as being obvious over Anderson in view of Spertell.

As per claim 24 and 25, Anderson does not teach size of vacuum passage in the medical device disposable, Although Spertell does not directly teach wherein said vacuum passage is approximately .020 inches wide and the vacuum passage is greater than approximately .010 inches when said medical device disposable is attached to an applicator, however, Spertell indirectly give the passage width by describing other relative dimensions and the drawings(col 8, ln 57-63, Fig.7). Spertell mentions the vacuum flow is sufficient and according to Fig. 7, 54, it should not be less than 0.5 mm = 0.02 inches. It would have been obvious to one skilled in the art to make the vacuum passage width between 0.01 to 0.02 inches so as to provide an efficient size conduit while minimizing space and waste.

Claims 11-12 lack an inventive step under PCT Article 33(3) as being obvious over Spertell in view of Morris, and further in view of US 2004/0049251 A1 (Knowlton).

As per claim 11 and 12, Spertell discloses a medical device disposable, but fails to teach a smooth and radiused surface, Knowlton discloses method and apparatus wherein said tissue chamber includes a chamber wall extending from said tissue opening to approximately said tissue contact surface, said wall including a substantially smooth, radiused surface(para[0024]) having a radius of approximately three-sixteenths of an inch(para[0201], note: three sixteenths of an inch = 0.187 inches) . It would have been obvious to one skilled in the art apply the surface of the chamber taught by Knowlton to the device of Spertell so that the tissue chamber can be closer and better contacted with the treated surface of tissue.

Claim 13 lacks an inventive step under PCT Article 33(3) as being obvious over Spertell in view of Morris, and further in view of US 6,457,476 B1 to Elmer et al (hereinafter "Elmer").

As per claim 13, Spertell discloses a medical device disposable, but fails to disclose a compliant member, Morris discloses a flexible member, but fails to teach the hardness of the material. Elmer discloses an applicator wherein said compliant member has a durometer density rating of approximately A60 (col 9, ln 50-53). It would have been obvious to one skilled in the art to utilize the material disclosed by Elmer combine the devices disclosed by Spertell and Morris so that the device has a better contacting and sealing with the treatment surface.

Claims 1-26 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.